

TOYA115.015APC



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Kimura, et al.  
Appl. No. : 10/553,092  
Filed : October 13, 2005  
For : BIOLOGICALLY ACTIVE  
SUBSTANCE-IMMOBILIZED  
DEVICE  
Examiner : Unknown

Group Art Unit Unknown

CERTIFICATE OF MAILING

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

May 23, 2006

(Date)

*Che S. Chereskin*  
Che Swyden Chereskin, Ph.D., Reg. No. 41,466

REQUEST FOR CORRECTED FILING RECEIPT

Commissioner for Patents  
P.O. Box 1450  
Office of Initial Patent Examination  
Customer Service Center  
Alexandria, VA 22313-1450

Dear Sir:

Applicants hereby request that the Official Filing Receipt, a copy of which is enclosed, be corrected to reflect the true title of the invention. Presently, the Filing Receipt incorrectly shows the title as Element having bioactive substance fixed thereto. The correct title is BIOLOGICALLY ACTIVE SUBSTANCE-IMMOBILIZED DEVICE. Documentation supporting this requested correction is provided herewith.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated:

May 23, 2006

By:

*Che S. Chereskin*  
Che Swyden Chereskin, Ph.D.  
Registration No. 41,466  
Agent of Record  
Customer No. 20,995  
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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
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APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT. CLMS	IND CLMS
10/553,092	10/13/2005	1645	900	TOYA115.015APC		12	1

CONFIRMATION NO. 9129

20995  
 KNOBBE MARTENS OLSON & BEAR LLP  
 2040 MAIN STREET  
 FOURTEENTH FLOOR  
 IRVINE, CA 92614

## FILING RECEIPT



\*OC000000018825931\*

Date Mailed: 05/17/2006

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

## Applicant(s)

Naoki Kimura, Chiba-shi, JAPAN;  
 Ryuichi Oda, Chiba-shi, JAPAN;  
 Gen Masuda, Chiba-shi, JAPAN;  
 Toshifumi Hashiba, Chiba-shi, JAPAN;  
 Kazutoshi Hayakawa, Chiba-shi, JAPAN;

**Power of Attorney:** The patent practitioners associated with Customer Number 20995.

**Domestic Priority data as claimed by applicant**

This application is a 371 of PCT/JP04/05498 04/16/2004

**Foreign Applications**

**Acceptable Request to Retrieve Priority Application Received?**

JAPAN 2003-114411 04/18/2003

NO

**If Required, Foreign Filing License Granted:** 05/16/2006

**The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is** **US10/553,092**

**Projected Publication Date:** 08/24/2006

**Non-Publication Request:** No

BEST AVAILABLE COPY

Early Publication Request: No

Title

~~5b BIOLOGICALLY ACTIVE SUBSTANCE - IMMOBILIZED DEVICE~~~~Element having bioactive substance fixed thereto~~

Preliminary Class

435

## PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

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### LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

### GRANTED

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date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

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#### **NOT GRANTED**

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

**NATIONAL PHASE  
UTILITY APPLICATION**

**Transmittal to the (DO/EO/US)  
Under 35 USC 371**

Attorney Docket No.: TOYA115.015APC  
First Named Inventor: Naoki Kimura  
Int'l Application No.: PCT/JP2004/005498  
Int'l Filing Date: April 16, 2004  
Priority Date Claimed: April 18, 2003  
Title: BIOLOGICALLY ACTIVE SUBSTANCE-IMMOBILIZED  
DEVICE (amended)  
Express Mail Label No.: EV 718229535 US

**Direct all correspondence to Customer No.: 20995**

Date: October 13, 2005

Page 1 of 2

**Mail Stop PCT**

United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria VA 22313-1450

The following enclosures are transmitted herewith to be filed in the patent application of:

**Inventors:**

1. Naoki Kimura
2. Ryuichi Oda
3. Gen Masuda
4. Toshifumi Hashiba
5. Kazutoshi Hayakawa

**APPLICATION ELEMENTS:**

- (X) This is a FIRST submission of items concerning a filing under 35 U.S.C. § 371.
- (X) This is an Express Request to begin national examination procedures (35 U.S.C. § 371(f)).
- (X) The U.S. has been elected (Article 31).
- (X) A copy of the International Application as filed (35 U.S.C. § 371(c)(2)) has been communicated by the International Bureau. A copy of Form PCT/IB/308 is enclosed.
- (X) An English translation of the International Application as filed is attached hereto.
- (X) Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. § 371(c)(3)) have not been and will not be made.
- (X) An Oath or Declaration signed by the inventors (35 U.S.C. § 371(c)(4)).

**OTHER APPLICATION PARTS:**

- (X) Preliminary Amendment in 5 pages.
- (X) Sequence Listing on paper in 2 pages
- (X) Sequence Listing in CRF format (in duplicate)
- (X) Recordation form cover sheet and Assignment in 3 total pages (cover sheet & assignment).
- (X) An Information Disclosure Statement and PTO/SB/08 equivalent listing 3 references for consideration and enclosing 2 of those references.
- (X) Copy of Form PCT/IB/304.

**NATIONAL PHASE  
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Under 35 USC 371**

Attorney Docket No.: TOYA115.015APC  
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**Direct all correspondence to Customer No.: 20995**

Date: October 13, 2005

Page 2 of 2

(X) International Application as published (1st page).

(X) Return prepaid postcard.

**FILING FEES:**

FEE CALCULATION				
FEE TYPE & DETERMINATION		LARGE FEE	CALCULATION	TOTAL
Basic Filing Fee under 1.492(a)		1631 (\$300)		\$300
Search Fee under 1.492(b) (enter one in TOTAL column)				
(1) USPTO was ISA and claims are novel		1640 (\$0)		\$400
(2) USPTO was the ISA		1641 (\$100)		
(3) Foreign Search Report Enclosed		1642 (\$400)		
(4) No Search Report Enclosed		1632 (\$500)		
Examination Fee under 1.492(c) (enter one in TOTAL column)				
(1) USPTO was IPEA & claims satisfy Art. 33 (1)-(4))		1643 (\$0)		\$200
(2) Non US IPEA / Noncompliant Claims		1633 (\$200)		
Excess Claims	12 - 20 = 0	1615 (\$50)	0 x 50 =	\$0
Excess Ind. Claims	1 - 3 = 0	1614 (\$200)	0 x 200 =	\$0
Assignment		8021 (\$40)	* x 40 =	\$40
			<b>TOTAL FEE DUE</b>	<b>\$940</b>

(X) A check in the amount of \$940 to cover the Total Fee Due is enclosed.

The Commissioner is hereby authorized to charge any additional fees which may be required, now or in the future, or credit any overpayment to Account No. 11-1410.



Che Swyden Chereskin, Ph.D.

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Agent of Record

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TOYA115.015APC



PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant	:	Kimura, et al.
Int'l Appl. No.	:	PCT/JP2004/005498
Int'l filing date	:	April 16, 2004
For	:	BIOLOGICALLY ACTIVE SUBSTANCE-IMMOBILIZED DEVICE (AMENDED)
Examiner	:	unknown
Group Art Unit	:	unknown

**PRELIMINARY AMENDMENT**

**Mail Stop Amendment**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Preliminary to examination on the merits, please amend the above-captioned U.S. application as follows.

**Amendments to the Specification** begin on page 2 of this paper.

**Amendments to the Claims** are reflected in the listing of claims which begins on page 3 of this paper.

**Remarks/Arguments** begin on page 5 of this paper.

Int'l Appl. No. : CT/JP2004/005498  
Int'l filing date : April 16, 2004

## AMENDMENTS TO THE SPECIFICATION

*Please change the title as follows:*

~~ELEMENT HAVING BIOACTIVE SUBSTANCE FIXED THERETO~~BIOLOGICALLY  
ACTIVE SUBSTANCE-IMMOBILIZED DEVICE

*On page 1 of the Specification, after the Title of the Invention and before the Technical Field,  
please insert the following section:*

### Related Applications

This application is the U.S. National Phase under 35 U.S.C. § 371 of International Application PCT/JP2004/005498, filed April 16, 2004, which was published in a language other than English, which claims priority of JP Patent Application No. 2003-114411, filed April 18, 2003.

*On page 54 before Claim 1, please amend as follows:*

WHAT IS CLAIMED IS: CLAIMS



### AMENDMENTS TO THE CLAIMS

1. (Original) A biologically active substance-immobilized device, which comprises a base particle comprising a core particle and an organic compound having two or more hydrophilic groups and immobilized on the core particle by a chemical bond and a biologically active substance bonded to the base particle via the organic compound.

2. (Currently amended) The device according to claim 1, ~~which is used~~monodispersed in an aqueous medium.

3. (Currently amended) The device according to claim 1 ~~or 2~~, wherein the base particle has an average particle diameter of 0.01 to 100  $\mu\text{m}$ .

4. (Currently amended) The device according to ~~any one of claims 1 to 3~~claim 1, wherein the base particle has a spherical or substantially spherical shape.

5. (Currently amended) The device according to ~~any one of claims 1 to 4~~claim 1, wherein at least one of  $CV_b$  ratio and  $CV_c$  ratio defined by the following equations is 0.6 to 3.0:

$$CV_b \text{ ratio} = CV_1/CV_3$$

$$CV_c \text{ ratio} = CV_2/CV_3$$

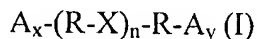
$$CV_1 = (\text{Standard deviation of core particle diameter}/\text{Average core particle diameter}) \times 100$$

$$CV_2 = (\text{Standard deviation of base particle diameter}/\text{Average base particle diameter}) \times 100$$

$$CV_3 = (\text{Standard deviation of device diameter}/\text{average device particle diameter}) \times 100$$

6. (Currently amended) The device according to ~~any one of claims 1 to 5~~claim 1, wherein the core particle and the biologically active substance are bonded by a reaction with a functional group selected from the group consisting of carbodiimide group, ester group, carbonate group, epoxy group and oxazoline group.

7. (Currently amended) The device according to ~~any one of claims 1 to 6~~claim 1, wherein the organic compound is a compound represented by the following formula:



wherein  $A_x$  and  $A_y$  independently represent a segment having a functional group that exhibits hydrophilicity and may be identical or different, R independently represents an organic group of two or more valences, X independently represents carbodiimide group, epoxy group or oxazoline group, and n is an integer of 2 to 80, preferably 2 to 40.

8. (Currently amended) The device according to ~~any one of claims 1 to 7~~claim 1, wherein the biologically active substance is selected from a nucleic acid, protein, hapten and saccharide.

9. (Currently amended) The device according to ~~any one of claims 1 to 8~~claim 1, which is for detecting or measuring a second biologically active substance contained in a sample by using a specific bond of the biologically active substance and the second biologically active substance in the sample.

10. (Currently amended) The device according to ~~any one of claims 1 to 8~~claim 1, wherein the biologically active substance is an agent for therapeutic treatment of a disease.

11. (New) The device according to claim 7, wherein n is an integer of 2 to 40.

12. (New) A method of detecting or measuring a second biologically active substance in a sample comprising the step of binding the second biologically active substance to the biologically active substance bound to the base particle in the device of claim 1.

Int'l Appl. No. : CT/JP2004/005498  
Int'l filing date : April 16, 2004

### REMARKS

Claims 2-10 have been amended and claims 11-12 have been added to conform with the rules of practice before the U.S. Patent and Trademark Office. The specification has been amended to recite the International Application and priority application. Claims 1-12 are presented for examination. No new matter is added by this amendment.

Enclosed herewith are: (1) a paper copy of the Sequence Listing, and (2) a computer readable version of the Sequence Listing.

### VERIFICATION UNDER 37 C.F.R. § 1.821 (f)

All of the sequences in the attached Sequence Listing are included in the application as filed. As required under 37 C.F.R. § 1.821 (f), I hereby verify that the data on the enclosed disk and the paper copies of the Sequence Listing are identical.

### **Conclusion**

Should there be any questions concerning this application, the Examiner is invited to contact the undersigned agent at the telephone number appearing below. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: Oct. 13, 2005

By: Che S. Chereskin  
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